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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,328	05/19/2005	Daniel Zimmerman	CS-118	3294

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HAHN & VOIGHT PLLC
1012 14TH STREET, NW
SUITE 620
WASHINGTON, DC 20005

EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,328	ZIMMERMAN ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims 1-12 and 18 drawn to an invention nonelected with traverse in the reply filed on 8/24/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants continue to traverse the restriction requirement, particularly the species election. First, applicant should note that the common technical features of SEQ ID nos 7, 9, and 18 were noted, and all three of these sequences were examined in the action mailed 9/25/2007. See for example pages 4-5, which repeatedly refer to all three of these sequences in setting forth the rejections. Applicant also argues that unity of election practice does not apply to species election. However, to quote PCT Rule 13.3:

> 13.3..*Determination of Unity of Invention Not Affected by Manner of Claiming* The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

In independent claim 1, there are three alternative disease conditions. In independent claim 6, there are two alternative disease conditions. In independent claim 12, there are two alternative disease conditions. In independent claim 13, there are three alternative disease conditions; dependent claim 15 adds three more. Therefore, even though these claims were generally grouped together under the category of "body-treating methods," each independent claim presents a Markush group of disease conditions, in addition to a Markush group of

peptides. The disease conditions are not "of a similar nature," as required for unity of invention in Annex B, as all have different etiologies, demonstrate different symptoms, involve different groups of patients, and are conventionally treated by very different methods. Therefore, election of species of both disease conditions and treating peptides was appropriate under unity of invention considerations.

Response to Amendment

The declaration under 37 CFR 1.132 filed 12/26/2007 is sufficient to overcome the 103 rejection of claims 13-15 and 17 over Zimmerman et al.

Applicant states that it is incorrect to state that position 1 of SEQ ID NO:7 is "Asp or cyclohexylalanine or D- alanine ." However, this is precisely what is set forth in the Other Information for position 1 : "X is A or D and when X is A, then A is either cyclohexylalanine or D-alanine." Therefore, X is D (=Asp) or cyclohexylalanine or D-alanine. There are still conflicts between the Sequence Listing and the specification; for example paragraph 12 recites acetylClAc or BrAc at position 1 of SEQ 18 and SEQ 7, which is not included in the Other Information for SEQ 18 and SEQ 7. Also, the specification disagrees with the Listing on the structure of SEQ ID NO:6: the specification has two Glu residues (EE) near the beginning, and the Listing only has one.

For purposes of examination, SEQ ID Nos 7, 9, and 18 will be treated as they are defined in the Listing filed 12/23/2005, with additional options of acetylaspartate, propionylaspartate, bromoacetylaspartate, or

chloroacetylaspartate at position 1. However, this treatment does not relieve applicant of amending the Sequence Listing to reflect this change.

Claim Rejections - 35 USC § 112

Claims 13-17 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use of derG, SEQ 7, 9, and 18 as an adjuvant and for a method of ameliorating zosteriform herpesvirus by administering derG before infection, does not reasonably provide enablement for the broadly claimed method for treating infectious conditions, for reasons of record. Applicant argues that a single example of treating one species of infectious disease using one species of peptide bears a reasonable correlation to treatment of any disease condition caused by viruses by any of the peptide species. Applicant further argues that the variations among the peptide species involve conservative substitutions, which would not be expected to alter biological activity in an unpredictable manner. Applicant argues that VLIGA are all nonpolar and a conservative substitution. This would be convincing if the substitution at position 6 were limited to these amino acids. However, in SEQ 9 this position includes the positively charged lysine and the large hydrophobic phenylalanine, and in SEQ 18 this position is lysine. These are changes which would reasonably be expected to affect the biological activity of a small peptide. Furthermore, zosteriform herpes, which involves a neurotrophic virus, does not serve as an accepted model for treatment of all other viral disease conditions, which are as varied as influenza infection of the respiratory tract, HIV infection of the immune system, papillomavirus infection of the cervical epithelium, hepatitis

C infection of liver, etc. Therefore the arguments are not convincing and the rejection is maintained.

Double Patenting

Claims 13-16 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 11/696124, for reasons of record. Applicant argues that the '124 claims related to methods for treating avian flu using SEQ ID NO:97 as an adjuvant in conjunction with a vaccine. Applicant argues that there is no overlap because the claims of this application do not recite an adjuvant in conjunction with a vaccine. However, claim 14 specifically recites adjuvant use, and claim 16 specifically recites administration with an antigen given at the same time. Therefore, use as an adjuvant in conjunction with a vaccine does overlap with these claims.

Claims 13-15 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6572860 in view of Zimmerman et al WO 01/89286, for reasons of record. Applicant argues that the rejection is improper because two references have been cited. However, citing prior art as a secondary reference is permissible in an obviousness-type provisional double patenting rejection, see form paragraph 8.37 in MPEP 804; Zimmerman WO 0189286 is a published document, available as prior art, and used as a secondary reference.

Claims 13-15 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-9 of U.S. Patent No.

6951647, for reasons of record. Applicant argues that the pending claims relate to methods of treating diseases and conditions, whereas the copending claims recite a method of eliciting a cellular immune response. However, eliciting a cellular immune response and treating a disease are not necessarily patentably distinct processes: a disease may be treated by eliciting a cellular immune response. One set of claims describes the process in terms of a mechanism of action (eliciting a cellular immune response) and the other in terms of an end result (treating an infectious condition), but both encompass administering the same peptide to the same host.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

3/31/08